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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/482,682	VON SEGGERN ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-23,41,47,69 and 95-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5-8* is/are allowed.

6)☒ Claim(s) *1,2,4,9,11-13,15-18,20-23,41,47,69 and 95-103* is/are rejected.

7)☒ Claim(s) *10,14 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/9/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In the paper submitted Match 9, 2004, applicant amended claims 1, 2, 6-8, 13, 14, 16-20, 47, 69, 97-99, 102 and 103. Claims 1, 2, 4-23, 41, 47, 69 and 95-103 are pending and under consideration.

Due amendments to the claims and persuasive arguments, the teachings of Sheay et al., Kaufman et al., Curiel, Wickham et al. and Branellec et al. are no longer relevant to the instant claims. However, new grounds of rejection are required due to a further consideration of the prior art.

Inventorship

In view of the papers filed March 9, 2004, the inventorship in this nonprovisional application has been changed by the deletion of Paul Hallenbeck, Susan Stevenson and Yelena Skripchenko.

The petition to correct inventorship under 37 CFR 1.48(b) is **GRANTED**.

Accordingly, Paul Hallenbeck, Susan Stevenson and Yelena Skripchenko, are hereby deleted as inventors on this file.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Priority

Acknowledgment is made of the clarified language to the priority claim in the first line of the specification.

The issue regarding priority is moot because, as applicant has indicated, there is no intervening prior art.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on March 9, 2004 was filed after the mailing date of the first action on the merits on September 9, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Application 09/795,292, previously unavailable, has now been considered. The only application currently listed on the IDS that remains unavailable for consideration is 10/410,907, which has been lined thru. This application has not been completely scanned into the new PTO electronic database and is unavailable for order. Therefore, the application cannot be considered at this time.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41, 47 and 95-97 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 57, 58, 60, 65 and 66 of copending Application No. 09/795,292.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a method of producing an adenovirus particle by providing a packaging cell line that comprises a stably integrated first nucleic acid molecule encoding an adenovirus structural protein and a TPL sequence linked to an intron containing an RNA processing signal, where the TPL sequence comprises a first and second different TPL exons or a first, second and third different TPL exons and the cell complements a deficient gene in a recombinant adenovirus genome to produce an adenovirus particle. The structural protein is an adenovirus fiber protein. These limitations anticipate the method of '292, drawn to a method of producing an adenovirus vector with a cell complementing a fiber gene in a fiber-less adenovirus genome with a nucleic acid containing the same TPL formation that is stably integrated. Although the instant claims do not specifically recite "transfecting" the complementing cell with the nucleic acid expressing the fiber gene, the instant claims anticipate "providing" the nucleic acid encoding a fiber protein. The "providing" step necessarily anticipates any conventional means of nucleic acid delivery to a host cell.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 100 and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 100 requires that the nucleic acid molecule of claim 7 is contained in plasmid pCLF. Claim 101 states that the sequence of the nucleic acid of claim 100 is SEQ ID NO: 8. Both of these claims ultimately depend from claim 6, which requires:

a) a first and second different TPL exons from different adenoviruses, or in a non-native order or both or,

b) a first, second and third same or different TPL exons, wherein at least two of the different TPL exons are from different adenoviruses, or in a non-native order or both.

It is disclosed in the specification on page 66, lines 18-28 that pCLF comprises a "partial" tripartite leader sequence, which is partial exon 1 followed by the entire exon 2 and entire exon 3 from Ad5. Therefore, the components of pCLF are incongruous with the requirements of claim 6 because all of the exons within the pCLF are derived from the same adenovirus, Ad5, and are in native order, i.e. partial exon 1, exon 2 and exon 3. The incongruency between the required limitations of claim 6 and the actual components of pCLF render claims 100 and 101 unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 18, 100, 102 and 103 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant states that the deposit of biological materials is not necessary if the materials, or starting materials, are known and readily available to the public, or obtainable by a repeatable method set forth in the specification. Applicant asserts that since the complete nucleotide sequences of each plasmid are provided in the sequence listing as well as detailed protocols in the specification, one of skill in the art can readily make the claimed material.

Applicant's arguments as well as a review of the teachings in the disclosure pointed to by applicant have been fully considered, but are found unpersuasive.

It is maintained that the claimed materials are required to be deposited because the starting materials to make the claimed plasmids do not appear to be readily available. For example, the starting material for pCLF is made up of several plasmids. One of these starting plasmids is pRD112a of Sheay et al., see page 66, starting at line 13. Contrary to applicant's assertions, pRD112a of Sheay et al. is not a readily available public material. One skilled in the art would be required to obtain a copy of the Sheay et al. reference and construct pRD112a according to the teachings of Sheay et al. to obtain one of the starting materials required for the construction of pCLF. The disclosure then teaches that a BglII fragment containing Ad5 TPL from pRD112a is excised and inserted into the BamH1 site of pCDNA3/Fiber (depicted in Figure 3), which is derived from "pcDNA3" from Invitrogen™. Since pCDNA3/Fiber is also not readily available public material, the skilled artisan would be required to make this plasmid as well. Starting on page 65, the disclosure discusses the process for making pCDNA3/Fiber. For this plasmid, the skilled artisan would be required to synthesize primers and amplify the Ad5

fiber gene and insert the gene into "pcDNA3". It is noted that while the skilled artisan may be able to purchase "pcDNA3" from Invitrogen™, Invitrogen™ is not a recognized deposit facility and there is no identifiable characteristics of this "pcDNA3" other than its name. Since there are no identifiable characteristics of this plasmid, the skilled artisan would be unable to reconstruct the structural components of the plasmid or purchase the plasmid if it were no longer available for sale. Therefore, contrary to applicant's assertions, the starting materials required for the construction of the instantly claimed plasmids are not publicly available materials.

The instantly claimed plasmids, pCLF, pDV60, pDV67, pDV69, pDV80 and pDV90 are recited elements in the claims. These recited elements are necessarily required to practice the invention. Therefore, these elements must be known and readily available to the public or obtainable from a repeatable method set forth in the specification, or otherwise readily available to the public.

While nucleotide sequences for each of the claimed plasmids are disclosed, these sequence designations do not appear in claims 9, 18, 100, 102 and 103. The plasmids, as identified by the designated name recited in the claims, are the required elements. Further, claims 102 and 103 require a plasmid "having all of the identifying characteristics of a plasmid deposited at the ATCC under accession no....". One skilled in the art would be unable to make the claimed plasmid or identify all of the characteristics of the claimed plasmids without access to the deposited source.

Applicant's deposit statement in the specification bridging pages 88-89 does not indicate the extent of public availability. The MPEP § 2404.01 states that: "A mere reference to a deposit of biological material itself does not necessarily mean that the biological material is readily

available." If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808. Receipt of an affidavit or deposit stating the items described above would obviate this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Logan et al.

Applicant is persuasive that there is ample support in the specification for nucleic acid sequences "not normally found together in nature".

On page 20 of the response, applicant reiterates claim 1 and argues that Logan et al. do not anticipate an isolated nucleic acid molecule containing a TPL exon in which two of the exons are from the same adenovirus, but in different order.

Applicant's arguments and a review of the reference have been fully considered, but are found unpersuasive. Contrary to applicant's assertions, Logan et al. clearly anticipate an isolated

nucleic acid molecule comprising two TPL exons from the same adenovirus in an order "not normally found together in nature", see "sub 360-L1, 3" in Figure 1 on page 3656. Therefore, the rejection is proper and in agreement with all of the relevant case law cited by applicant.

Claim 2 is drawn to the same nucleic acid sequence of claim 1 operatively linked to an intron containing an RNA processing signal.

Logan et al. teach that in place of the E1A transcriptional control sequences, each construct comprises a 241-bp untranslated segment that includes the major late transcriptional control region to enhance E1A mRNA transcription, see the first full sentence of the first column on page 3656. This teaching anticipates claim 2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Logan et al. as applied to claims 1 and 11 above, and further in view of Hodges et al. (Molecular Pharmacology. 1995; 48: 905-918).

Claim 4 requires that the intron is native adenovirus intron 1.

Logan et al. do not teach that the 241-bp segment is adenovirus intron 1.

However, Hodges et al. teach the insertion of an adenovirus intron 1 in the sense and antisense orientation, see Figure 1A and the first two constructs in Figure 1B.

One of ordinary skill in the art at the time the invention was made would have been motivated to insert the adenovirus intron 1 of Hodges into the construct of Logan et al. because Hodges et al. teach that adenovirus intron 1, oriented in the sense direction, induced the highest level of expression activity, see Figures 2A, 3B and 4A-D. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for inserting adenovirus intron 1 into the construct of Logan et al. because Logan et al. teach insertion of a segment that enhances transcription and Hodges et al. teach that insertion of adenovirus intron 1 induces the highest level of transcription. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 12, 13, 15-17, 20-23, 41, 47, 69 and 95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan et al. as applied to claims 1, 2 and 11 above, **or** the teachings of Kaufman et al. or Sheay et al. in the alternative (both references cited in the previous Office action), and further in view of Caravokyri et al. (Journal of Virology. 1995; 69 (11): 6627-6633), Curiel et al. (US 5,871,727, cited in the previous Office action).

With respect to the teachings of Sheay et al. and Kaufman et al., applicant persuasively argues that the references, in the alternative, do not teach at least two TPL exons from different adenoviruses and/or in non-native order. However, claims 12, 41, 95, 96 and 97 have not been amended to recite the same recitations required by claims 1 and 6. Claims 12, 41 and 95-97 require nucleic acids comprising first and second different TPL exons or the first, second and third same or different TPL exons.

Logan et al. teach sub 360-L1, 2, 3, which comprises the three, full-length TPL exons.

Sheay et al. teaches plasmid pRD112a, which encodes adenovirus type 2 tripartite leader sequences, see Figure 1.

Applicant correctly points out on page 27 that Kaufman et al. teach plasmids D20 and D15, encoding complete TPL exon 1, complete TPL exon 2 and a portion of TPL exon 3.

Therefore, the TPL exons of Logan et al. or Sheay et al. or Kaufman et al. are different. That is, the TPL exons 1, 2 and 3 of Logan et al. or Sheay et al. or Kaufman et al. are differentially designated 1, 2 and 3. Therefore, none of the TPL exons of Sheay et al. or Logan et al. or Kaufman et al. are the same and meet the claim requirements of claims 12, 41 and 95-97, requiring first and second "different" TPL exons.

Claims 12, 13 and 15-17 are drawn to an adenovirus packaging cell line comprising a stably integrated nucleic acid molecule comprising the nucleic acid of claims 6-8. Claims 20-23 state that the cell expresses an early protein and a fiber gene under an inducible promoter. Claims 41, 47, 95-97 are drawn to a method of producing an adenovirus particle by providing a packaging cell line comprising the instant stably integrated nucleic acid comprising TPL exons 1-3 and a fiber protein that produces adenovirus particles by complementation. Claim 69 lists specific cell lines.

As applicant points out on page 36 of the response, Sheay et al. nor Kaufman et al. teach or suggest packaging cell lines containing stably integrated TPL sequences and/or any adenovirus structural proteins. It is noted that the same is true for the teachings of Logan et al.

Stably integrating adenovirus nucleotide sequences into a host cell genome to complement genes required by homologous gene-deficient adenoviruses is routine in the prior art, see the teachings of Caravokyri et al. for example. Caravokyri et al. teach a 293 packaging

cell lines containing nucleotide sequences that complements pIX-deficient adenoviruses under the control of an inducible promoter, see the first paragraph of the results section on page 6629 for example. One of ordinary skill in the art at the time the invention was made would have been motivated to

None of the references teach complementing an adenovirus structural protein, such as an Ad3 head domain and an Ad5 tail domain or an Ad5 head domain and an Ad3 tail domain or a fiber gene.

Curiel teach a plasmid comprising a chimeric fiber gene encoding the tail of Ad5 and the head of Ad3, see Figure 13, column 16, line 64 to column 17, line 34 and column 24, lines 49-67.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the TPL sequences of Sheay et al. or Kaufman et al. or Logan et al. with the chimeric adenovirus fiber gene of Curiel to increase the translational efficiency of the heterologous chimeric fiber sequences of Curiel, see the abstract and the last paragraph of Kaufman et al.; or the high transcription products of Logan et al. with sub 360-L1, 2, 3; or to enhance expression of the chimeric construct, see Table 1 of Sheay et al. One of ordinary skill in the art at the time the invention was made would also have been motivated to express the chimeric fiber gene of Curiel using the TPL sequences of Sheay et al. or Kaufman et al. or Logan et al. to retarget recombinant adenoviruses, see Figure 13, column 16, line 64 to column 17, line 34 and column 24, lines 49-67 of Curiel. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of combining the TPL sequences of Sheay et al. or Kaufman et al. or Logan et al. with the chimeric adenovirus fiber gene of Curiel because

TPL sequences are present in native adenoviruses to express adenovirus genes and are shown by Logan et al. to induce high expression of a gene product and the chimeric fiber gene of Curiel is derived from adenoviruses. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for stably integrating the TPL sequences of Logan et al. or Sheay et al. or Kaufman et al. with the chimeric fiber gene of Curiel et al. into a cell by conventional methods in the art, demonstrated by Caravokyri et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Regarding the teachings of Curiel et al., applicant argues that the reference does not teach or suggest obtaining enhanced expression of a gene. However, this is not a limitation recited in the claims. Applicant also asserts that the combination of references do not lead to a construct containing TPL exons that are the same or from different adenoviruses or in non-native order. However, as discussed above, claims 12, 41 and 95-97 do not require these limitations of the TPL exons.

Claims 98 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over Logan et al. as applied to claims 1, 2 and 11 above, **or** the teachings of Kaufman et al. or Sheay et al. in the alternative (both references cited in the previous Office action), and further in view of Caravokyri et al. (Journal of Virology. 1995; 69 (11): 6627-6633), Curiel et al. (US 5,871,727, cited in the previous Office action) and further in view of Branellec et al. (US 6,410,011 B1, cited in the previous Office action).

Claims 98 and 99 state that the adenovirus particle comprises a suicide gene.

None of the references teach an adenovirus particle comprising a suicide gene.

However, Branellec et al. teach an adenovirus comprising a suicide gene, see examples 1 and 2 bridging column 8, line 15 to column 9, line 60.

One of ordinary skill in the art at the time the invention was made would have been motivated to insert a suicide gene into the adenovirus of Logan et al. or Sheay et al. or Kaufman et al., respectively, in combination with Caravokyri et al. and Curiel et al. to inhibit proliferation of vascular smooth muscle cells, see claim 1 of Branellec et al., to increase the translational efficiency of the heterologous sequences, see the abstract and the last paragraph of Kaufman and the gene products of sub 360-L1, L2, L3 of Logan et al., or to enhance expression of the heterologous sequences, see Table 1 of Sheay et al. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing an adenovirus of comprising a suicide gene because the insertion site of the suicide gene, taught Branellec et al. does not interfere with the TPL sequences of Sheay et al. or Kaufman or Logan et al. or the chimeric fiber taught by Curiel. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

With respect to the teachings of Branellec et al., applicant notes the limitations not taught by the reference, such as packaging cell lines with stably integrated TPL sequences. However, these limitations are taught by Logan et al. or Sheay et al. or Kaufman et al. in combination with Caravokyri et al. and Curiel et al. In conclusion, all of the limitations recited in the claims have been taught by the combination of references with motivation for combination. Also, a reasonable expectation of success in producing the invention, absent unexpected results to the

contrary, has also been established. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art, absent unexpected results to the contrary.

Allowable Subject Matter

The prior art does not teach or suggest nucleic acids encoding all three adenovirus TPL exons from different adenoviruses or non-native order or both. Claims drawn to this subject matter would most likely receive favorable consideration. For example, the clause of section (a) in claims 1 and 2 should be deleted to distinguish over the teachings of Logan et al. In addition, similar limitations of the suggested claim language of claims 1, 2 and 6 into claims 12, 41 and 95-97 would also most likely receive favorable consideration.

As discussed by applicant on page 12 of the response, the previous Office action inadvertently objected to claim 5 as being dependent from a rejected claim. The claim is independent and is drawn to allowable subject matter, as previously indicated. Therefore, claim 5 is allowed.

Applicant's arguments regarding claims 6-8 are found persuasive. These claims are also patentable over the sub 360-L1,3 construct of Logan et al. While the sub 360-L1,3 construct of Logan et al. comprises two adenovirus TPL exons in non-native order, this construct produces less product than the native, full-length TPL construct, see "Tripartite Leader Facilitates Translation Late After Infection" bridging pages 3656 and Figures 2, 3 and Table 1. Therefore, there is no motivation to combine the sub 360-L1,3 construct of Logan et al. for the expression of a gene product.

Claims 10, 14 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowed claims: 5-8.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Patent Examiner, 1648